K071431

510(k) Summary
for
Globus Genesy Electro-Stimulator

SEP 2 1 2007

1. SPONSOR

Domino S.r.l.
Via San Felice, 4
31020 San Vendemiano (TV)
Italy

Contact Person: Giovanni Ciriani
Telephone: 860-539-1309

Date Prepared: Sep 01, 2007

2. DEVICE NAME

Proprietary Name:	Globus Genesy Electro-Stimulator
Common/Usual Name:	Electric Muscle Stimulator
Classification Name:	Powered Muscle Stimulator, Transcutaneous Electrical Nerve Stimulator (TENS), and Interferential Current Therapy Stimulator (IFC).

3. PREDICATE DEVICES

Chattanooga Vectra GENiSYS Stimulator Device K031077

4. DEVICE DESCRIPTION

The Globus Genesy Device is a programmable electro stimulator with multiple uses: Powered Muscle Stimulators, Transcutaneous Electrical Nerve Stimulator. Premodulated Current Therapy Stimulator, and Microcurrent Therapy Stimulator.

Each device in the family comes with a menu to select different stimulation programs. The Stimulation Programs have been subdivided in menus and submenus to facilitate use for various types of uses. The user can create and store protocols in the device for subsequent recall, and can store them and manipulate them in a PC for labeling and stimulation parameter changes.

The Globus Genesy electrical impulses trigger excitations that are transmitted to the muscle fibers, where they generate mechanical responses that result in muscle work. This work is used for muscle and range-of-motion rehabilitation therapies.

They also interact with the mechanism of pain generation and transmission in the nerve fibers; other stimulation currents interact directly with the affected body part to obtain the effect desired by the physician or licensed practitioner.

The core of the Globus Genesy device is a constant-current generator; a transformer guarantees insulation between outlet current utilized for the battery charger, and the circuits utilized for stimulation current. A micro-processor elaborates the menu selections and drives the constant-current generator that originates the electrical impulses for the electrostimulation. This is accomplished according to the parameters stored for that particular program. The user can regulate the current continuously from 0-120 mA.

5. INTENDED USE

The Globus Genesy Stimulator is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. It is intended to be used for therapy that adopts NMES, Russian, TENS, Premodulated Currents (IFC), and Microcurrent, waveforms.

The Globus Genesy is not intended to be used as an over-the-counter (OTC) device.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Domino S.r.l. Globus Genesy device and the Chattanooga Vectra GENiSYS Stimulator are similar in design and function. Both devices offer:

- biphasic waveforms, rectangular, symmetrical,
- asymmetric rectangular waveforms, compensated,
- monophasic rectangular waveforms,
- premodulated waveforms,
- Russian currents,
- Microcurrents,

Both the Globus and predicate devices are software-driven, electro-stimulator units that provide licensed practitioners with a variety of treatment currents for therapy.

The Globus Genesy and the Chattanooga Vectra GENiSYS devices are similar in technical characteristics and performance. The Globus Genesy device maximum current output and its maximum electric charge are very similar to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2007

Globus Sport and Health Technologies
% Mr. Giovanni Ciriani
Managing Partner
18 Eustace Dr.
West Hartford, CT 06110

Re: K071431
Trade Name: Globus Genesy 1100 Electro-Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Codes: IPF, GZJ, and LIH
Dated: August 31, 2007
Received: September 05, 2007

Dear Mr. Ciriani:

This letter corrects our substantially equivalent letter of September 25, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

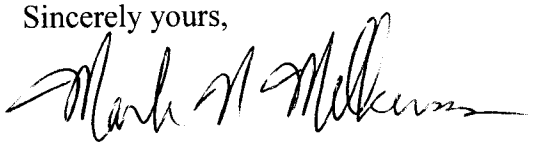
comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21

CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-3474. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K071431

Device Name: Globus Genesy 1100 Stimulator

Indications For Use:

The Globus Genesy 1100 Electro-stimulator should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. It is intended to be used for therapies employing NMES, Russian, and Premodulated Currents (IFC) to obtain the following:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

Additional Indications for Microcurrent, Premodulated Currents (IFC), NMES and TENS waveforms:

- Management of chronic, intractable pain
- Post-traumatic acute pain
- Post-surgical acute pain

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071431